DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS)

1. Technology Name: **Intramedullary Skeletal Kinetic Distractor – " ISKD"**

2. Manufacturer Name: **Orthofix Inc.**

3. Trade Brand of Technology: **Trademark Pending**

4. Brief Description of Service or Device:

The ISKD Limb Lengthening System is indicated for the lengthening of the tibia and the femur.

New Criteria

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

   The ISKD received marketing clearance on May 2, 2001 under 510(k) K010322.

6. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

   a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

      78.3 – Limb lengthening procedures – Bone graft with or without internal fixation devices or osteotomy; Distraction technique with or without cortiocotomy/osteotomy

(For the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/10_03_application.zip**)**
Note: The information provided on this tracking form will be made publicly available.

b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to http://www.cms.hhs.gov/paymentsystems/icd9 for more information.)

7. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to http://cms.hhs.gov/providers/hopps/apc.asp for more information.)

No application for pass-through payment code assignment has been submitted, as the service is provided only in in-patient settings.

Cost Criteria

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of 75 percent of one standard deviation above the average charges for the DRG(s) to which the technology or service is assigned.

Provide the following information to demonstrate the technology or service meets the criterion.

This information is pending and will be submitted under separate cover.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

9. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**- breakdown of the cost of all components used in the new technology).

10. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

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DRG 218 and/or 256.

11. What is the anticipated volume of Medicare cases involving of this technology (by DRG)?

Clinical Improvement

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

    a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

The ISKD System is a " closed" lengthening system. There are no fixation pins exiting the skin, thus eliminating this portal for entry of infectious organisms.

    b. List of published peer-review articles relevant to the new service or technology.

" The intramedullary skeletal kinetic distractor (ISKD): first clinical results of a new intramedullary nail for lengthening of the femur and tibia," Cole, J. Dean, et al; *Injury*, Int. J. Care Injured 32 (2001) S-D-139

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